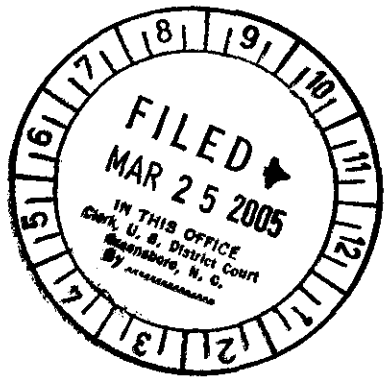
IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA



MICHAEL AND CYNTHIA DOE, individually and as guardians ad litem of MINOR CHILD DOE,	)	
Plaintiffs,	)	
v.	)	1:03CV00727
BAYER CORPORATION, Individually and as Successor-in-Interest to MILES, INC., an Indiana corporation; BAYER BIOLOGICAL PRODUCTS, a division of Bayer Corporation, an Indiana corporation,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

OSTEEN, District Judge

Plaintiffs Michael and Cynthia Doe, individually and as Guardians Ad Litem of Minor Child Doe (collectively, "Does"), bring this diversity action against Defendant Bayer Corporation ("Bayer").[1] Plaintiffs assert several state-law causes of action

[1] Originally, Plaintiffs also named as defendants Eli Lilly and Company and "Bayer Biological Products." Plaintiffs voluntarily dismissed Eli Lilly and Company without prejudice in October 2004. (Pls.' Notice Voluntary Dismissal Without Prejudice Def. Eli Lilly & Co. at 1.) Before being dismissed, Eli Lilly and Company filed a motion to dismiss Plaintiffs' claims, which remains pending before this court. That motion is moot.

Bayer Biological Products was dismissed as an improper party in this court's Memorandum Opinion and Order of November 1, 2004.

against Defendant arising out of personal injuries to Minor Child Doe, allegedly caused by in utero exposure to thimerosal.

Defendant moves for dismissal under Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction because Plaintiffs have not exhausted their remedies in the U.S. Court of Federal Claims (the "Vaccine Court"), as required by 42 U.S.C. § 300aa-21(a-b). As an alternative to dismissal, Defendant asks that this proceeding be stayed until the proceeding in the Vaccine Court is resolved. Defendant asserts a second alternative motion for a more definite statement of Plaintiffs' claims under Rule 12(e) of the Federal Rules of Civil Procedure. Finally, Defendant moves for Plaintiffs to supplement the record.

For the reasons set forth below, the motions will be denied.

I. BACKGROUND

The complaint sets out the following facts, which are presented in the light most favorable to Plaintiffs.[2]

Plaintiffs Michael and Cynthia Doe are the natural parents of Minor Child Doe. (Compl. ¶ 3.) In December 1994, while Cynthia was pregnant with Minor Child Doe, she was given an

[2] When considering a motion to dismiss, a court must construe the complaint in the light most favorable to the plaintiff, accepting as true all well-pleaded factual allegations. Randall v. United States, 30 F.3d 518, 522 (4th Cir. 1994).

injection of HypRho-D, a medical product manufactured by Bayer.[3] (Id. ¶ 22.) HypRho-D is an Rh-immune globulin compound that was administered to pregnant women to prevent Rh hemolytic disease in newborns, a result of a difference in Rh blood type between mother and child. (Def. Bayer's Mem. Supp. Mot. Dismiss, or Alt. Mot. Stay and/or Mot. More Definite Statement [hereinafter, "Bayer's Mot. Dismiss"] at 3 n.3.) If this Rh incompatibility is left untreated, the mother's immune system can attack the red blood cells in the fetal bloodstream. (Id.) HypRho-D was typically injected into a pregnant woman at around 28 weeks' gestation. (Compl. ¶¶ 16, 25.)

In manufacturing HypRho-D, Bayer included a preservative called thimerosal. (Id. ¶¶ 2, 16, 27, 31.) Thimerosal is an antiseptic compound that has been used as a preservative in various pharmaceutical preparations, including vaccines and Rh-immune globulin products like HypRho-D. (Id. ¶¶ 15-16.) Thimerosal consists of almost 50% organic mercury by weight. (Id. ¶ 15.) Mercury is toxic to humans, and a developing fetus may be especially sensitive to the effects of mercury exposure. (Id. ¶¶ 12-13, 20.) Prenatal exposure can cause harmful effects to the child's development, including severe neurological dysfunctions, developmental abnormalities, and neurodevelopmental

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[3] Bayer ceased manufacture of HypRho-D around 1996, in favor of a new formulation known as BayRho-D. (Compl. ¶ 24.)

disorders. (Id. ¶¶ 13, 21.) Once injected into a pregnant woman, thimerosal can be transported into the fetal blood stream, thus exposing the developing brain and other organs and tissues to organic mercury. (Id. ¶ 19.)

The Does allege Bayer knew or should have known of the dangerous effects of mercury exposure associated with thimerosal and had various duties to protect against injury. (Id. ¶ 37.) At the time, Bayer was aware that its product would be injected into pregnant women to prevent Rh hemolytic disease. (Id. ¶¶ 27-28.) Plaintiffs allege that Cynthia Doe's injection exposed Minor Child Doe to toxic levels of mercury and has caused him to suffer neurological damage. (Id. ¶ 34.) Specifically, he "has sustained mental, developmental and neurological incapacity and associated learning disabilities." (Id.) His damages include past and future medical expenses, as well as the expenses of "continual psychological, educational, occupational, rehabilitative and dietary therapies." (Id.) He also seeks recovery for loss of enjoyment of life, loss of future economic opportunity, and reduced future earnings capacity. (Id.) Also, as a result of the substantial and constant care Minor Child Doe requires, his parents have incurred injuries of their own. (Id.) They seek recovery for past and future medical expenses, the provision of past and future nursing care, emotional distress, and lost opportunities. (Id.)

Plaintiffs have filed an additional claim in the Vaccine Court. According to the Does, this claim is for "significant aggravation" of Minor Child Doe's preexisting injuries, allegedly caused by childhood vaccinations. (Pls.' Resp. Def.'s Mot. Dismiss & Supporting Mem. Law [hereinafter, "Pls.' Resp."] at 6-7.) In this court (the "District Court"), Plaintiffs contend the thimerosal in HypRho-D was the cause of the child's preexisting condition, and in the Vaccine Court they contend the thimerosal in his post-birth vaccinations significantly aggravated that preexisting condition. (Id.)

II. ANALYSIS

Plaintiffs bring multiple causes of action: negligence, negligent failure to warn, negligent misrepresentation, intentional misrepresentation and fraud, and unfair and deceptive trade practices, all in relation to the sale and distribution of HypRho-D. They also allege negligent infliction of emotional distress; inadequate design or formulation; breach of express warranty of merchantability; breach of implied warranties; gross negligence; and fraudulent, malicious, and willful or wanton conduct entitling them to punitive damages. They also seek recompense for the parents' loss of Minor Child Doe's services, comfort, society, and companionship, as well as for past and future medical and hospital expenses, and "loss of the services earnings and earning ability" of the child. (Compl. ¶ 99.)

Bayer asserts several arguments in its motion for dismissal. First, they argue that the District Court lacks subject matter jurisdiction because Plaintiffs have not yet exhausted their remedies in the Vaccine Court. Second, they argue that if this proceeding is not dismissed for want of subject matter jurisdiction, it should be stayed pending resolution of the Vaccine Court proceeding. Lastly, they move for a more definite statement of Plaintiffs' claims. These arguments will be addressed separately.

A. Exhaustion of Administrative Remedies in the Vaccine Court

Bayer argues that Plaintiffs' claims are governed by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (the "Vaccine Act" or the "Act"), and may not be brought in a federal district court until remedies in the Vaccine Court are first exhausted. (Bayer's Mot. Dismiss at 6-15.) Plaintiffs counter their claims are not for vaccine-related injuries, so are not governed by the Vaccine Act. (Pls.' Resp. at 5.)

1. Standard of Review

When a defendant's motion to dismiss challenges a federal court's subject matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of proving that such jurisdiction exists. Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982). When determining the existence of subject matter jurisdiction, a

court may consider the pleadings as evidence and may also look to evidence outside the pleadings without treating the inquiry as one for summary judgment. Evans v. B.F. Perkins Co., 166 F.3d 642, 647 (4th Cir. 1999). A court should dismiss an action for want of federal subject matter jurisdiction "only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." Id. (quoting Richmond, Fredericksburg & Potomac R.R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991)).

2. The Vaccine Act

The Vaccine Act creates a no-fault, administrative compensation scheme for people injured by vaccines. See 42 U.S.C. §§ 300aa-1 et seq. The scheme was created to ease the burden on both injured parties and vaccine manufacturers. Shalala v. Whitecotton, 514 U.S. 268, 269-70, 115 S. Ct. 1477, 1478 (1995). For injured parties, whose only mode of redress was the civil tort system or negotiated settlement with the vaccine manufacturer, recovery for their injuries took months or years and required substantial expenses for attorneys and court fees. H.R. Rep. No. 99-908, at 6 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347. For vaccine manufacturers, the costs of tort liability and the lack of affordable insurance to guard against this risk significantly reduced incentives to enter or remain in the vaccine market. Id. at 6-7, 1986 U.S.C.C.A.N. at 6347-48.

To address these problems, the Act allows injured parties to file a petition for compensation against the U.S. Government, rather than the vaccine manufacturer. Doe 2 v. Ortho-Clinical Diagnostics, Inc., 335 F. Supp. 2d 614, 620-21 (M.D.N.C. 2004). Petitioners follow a simplified procedure to prove causation before a specialized judge, or Special Master. Shalala, 514 U.S. at 270, 115 S. Ct. at 1478. Once causation is shown to a satisfactory level, the Special Master awards damages (subject to maximum caps), paid out of a special compensation fund financed by a tax on vaccines. See 42 U.S.C. § 300aa-10(a).

The Vaccine Act requires that claims of more than $1,000 brought against "a vaccine administrator or manufacturer" to recover for any "vaccine-related injury or death" must be brought in Vaccine Court first. 42 U.S.C. § 300aa-11(a)(2)(A). No civil action may be filed in state or federal court until the Vaccine Court has issued a judgment on the matter and the claimant has rejected that judgment.[4] See id. If a person with a vaccine-related injury brings an action in state or federal court without going to the Vaccine Court first, "the court shall dismiss the action." Id. § 300aa-11(a)(2)(B). The Vaccine Act also provides that, except as specified, "[n]o vaccine administrator or

[4] A litigant may also be allowed to sue in a state or federal court if the Vaccine Court fails to render a decision or enter judgment within a specified time period. See 42 U.S.C. § 300aa-11(a)(2)(A).

manufacturer may be made a party to a civil action . . . for damages for a vaccine-related injury." Id. § 300aa-11(a)(3). If a claimant has a pending, vaccine-related civil action, she is barred from filing in the Vaccine Court. Id. § 300aa-11(a)(5)(B). In essence, these provisions revoke the jurisdiction of civil courts over vaccine-related claims until plaintiffs first exhaust remedies with the Vaccine Court. See Doe 2, 335 F. Supp. 2d at 621.

To fall within the Vaccine Act's exhaustion provisions, a claim must involve a "vaccine-related injury" and must be brought against "a vaccine administrator or manufacturer." Moss v. Merck & Co., 381 F.3d 501, 504 (5th Cir. 2004). A "vaccine-related injury or death" is defined by the Act as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-33(5). The Vaccine Injury Table lists many recommended childhood vaccines, such as those containing pertussis, tetanus, polio, measles, mumps, and rubella. See 42 C.F.R. § 100.3. It does not list Rh-immune globulin products, such as HypRho-D. "Manufacturer" is defined as "any corporation, organization, or institution, whether public or private . . ., which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-33(3).

Over the past few years, the Vaccine Court has seen several thousand petitions alleging a causal connection between certain vaccinations, thimerosal, and "autism spectrum disorder" ("autism"). In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder v. Secretary Health & Human Servs., 2004 WL 1660351, *1 (Ct. Fed. Cl. July 16, 2004) (Ruling Mot. Disc. Merck Re: MMR Vaccine) [hereinafter, "Autism Discovery Ruling #1"]. Because scientific data on the causal connection is still developing and posing problems of proof and discovery, the Vaccine Court adopted a procedure to conduct a single discovery proceeding (the "Omnibus Autism Proceeding"). In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder v. Secretary Health & Human Servs., 2002 WL 31696785, *3 (Ct. Fed. Cl. July 3, 2002) (Autism Gen. Order #1) [hereinafter, "Autism General Order #1"]. This proceeding will create the "Autism Master File" as an evidentiary record for these cases. Id. To opt into the Omnibus Autism Proceeding and make use of the Autism Master File, petitioners (often referred to as "vaccinees") must file a Short-Form Autism Petition for Vaccinee Compensation ("Short-Form Petition"), which alleges that a measles-mumps-rubella (MMR) or thimerosal-containing vaccination (or some combination of the two) caused the vaccinee's autistic disorder, and that the

vaccinee's claim meets certain other criteria.[5] Id. Exs. A-B. Among these other criteria, vaccinees allege they have a vaccine-related injury, they have not filed any civil action for their injury, and they are filing the petition "within three years after the first symptom of the disorder, or within three years after the first symptom of a vaccine-caused significant aggravation of the disorder." Id. Ex. A.

Plaintiffs have filed a "significant aggravation" petition with the Vaccine Court. This type of claim is cognizable under the Vaccine Act. See 42 U.S.C. § 300aa-11(c)(1)(C) (requiring petitioners to allege they "sustained, or had significantly aggravated" an injury as a result of the vaccination). A significant aggravation claim requires petitioners to prove that a preexisting condition or injury was significantly aggravated by a vaccine. Williams v. Secretary Health & Human Servs., No. 90-3091V, 1998 WL 156967 at *9 (Ct. Fed. Cl. Mar. 18, 1998); see also, Whitecotton v. Secretary Health & Human Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996). "Significant aggravation" is defined as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness

[5] By filing the Short-Form Petition, petitioners also agree to stay proceedings on their cases until the Omnibus Autism Proceeding is concluded. In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder v. Secretary Health & Human Servs., 2002 WL 31696785, *4 (Ct. Fed. Cl. July 3, 2002) (Autism Gen. Order #1).

accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4) (emphasis added).

In their significant aggravation claim in the Vaccine Court, Plaintiffs must satisfy their burden of proof on causation. Whitecotton, 81 F.3d at 1102-03. There are two ways to make this showing: (1) by proving actual causation or (2) by using a burden-shifting analysis using the Vaccine Injury Table. Id. at 1107. The burden-shifting analysis requires the Special Master to first assess a three-part inquiry regarding whether the petitioner "'significantly aggravated an injury listed on the Vaccine Injury Table'" by looking at (a) the petitioner's condition before the vaccination, (b) the petitioner's current condition, and (c) whether the current condition constitutes a "significant aggravation" of the prior condition within the meaning of the statute. Id. at 1107 (quoting Reusser v. Secretary Dep't Health & Human Servs., 28 Fed. Cl. 516, 527 (1993)). If this three-part inquiry results in a finding of significant aggravation, then the Special Master continues to a fourth part and assesses (d) "whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the [Vaccine Injury] Table." Id. The government may rebut this showing by proving "the pre-existing condition was, in fact, the cause of the individual's post-vaccination significant aggravation." Id. The government may

also rebut this showing by proving that the injury was caused by a factor unrelated to the vaccine. Turner v. Secretary Health & Human Servs., 268 F.3d 1334, 1337 (Fed. Cir. 2001); see also 42 U.S.C. § 300aa-13(a)(1)(B).

Thus, to succeed on their significant aggravation claim in the Vaccine Court, the Does will have to show that Minor Child Doe had an existing neurodevelopmental disorder or other injury that was "change[d] for the worse" by one or more of his vaccinations (or any preservative contained therein). They will have to present evidence related to Minor Child Doe's vaccines to prove actual causation or to make out a prima facie case under the four-part test from Whitecotton. However, to succeed in the District Court, the Does will have to show that the thimerosal in HypRho-D, on its own, caused that preexisting injury. In the District Court, the Does will have to present evidence related to HypRho-D to prove actual causation.

3. Are the Does' Claims Covered by the Vaccine Act?

In this case, Plaintiffs argue that their suit in this court alleging initial causation of a neurodevelopmental disorder is distinct from their petition in the Vaccine Court alleging "significant aggravation" of a preexisting condition. (Pls.' Resp. at 6-8.) Defendant counters that the proceedings here are, practically speaking, "vaccine-related" because they are so intertwined with the Vaccine Court proceedings that they cannot

be considered separately.[6] (Bayer's Mot. Dismiss at 4-6.) Defendant argues that the proceedings substantially overlap in two ways: (1) the injuries for which the Does seek recovery are the same in both proceedings, and (2) the issue of whether and to what extent exposure to thimerosal caused Minor Child Doe's injuries will be a dispositive issue - and the subject of much discovery and argument - in both proceedings.

a. Plaintiffs' Injuries

Bayer argues the claim of "significant aggravation" is no different than a claim to recover for the cumulative effects of exposure. (See Bayer's Mot. Dismiss at 8-11; Bayer's Reply at 7-8.) Essentially, Bayer argues there is substantial overlap, and thus no practical distinction, between the claims brought in this court for injuries from the prenatal exposure to thimerosal (via HypRho-D) and the claims brought in Vaccine Court for injuries from the post-natal exposure to thimerosal (via childhood vaccinations). Bayer contends Plaintiffs' use of two forums splits what should be a single claim in order to avoid the administrative exhaustion requirements and award limits in the Vaccine Court. (Bayer's Mot. Dismiss at 5-7.) The court finds that Plaintiffs' claims here are distinct from their claims in the Vaccine Court.

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[6] Although Defendant makes arguments regarding the issues of injury and causation, it does not by virtue of these arguments concede any disputed facts related to injury and causation.

Bayer relies heavily on Agbebaku v. Sigma Aldrich, Inc., to argue that the Does' injuries are vaccine-related. No. 24-C-02-004243, slip op. (Md. Cir. Ct. June 19, 2003), cert. denied, 844 A.2d 427 (Md. 2004). In Agbebaku, the plaintiffs sued various defendants for injuries caused by exposure to thimerosal and for exacerbation of those injuries caused by environmental pollution from coal-burning power plants. Id. at 2. The thimerosal at issue in that case was contained both in vaccines and in an Rh-immune globulin compound called RhoGAM. Id. at 27. The Maryland Circuit Court dismissed the claims against the manufacturers of RhoGAM on the ground that those claims were vaccine-related and required exhaustion of remedies in the Vaccine Court. Id. at 27-28. In Agbebaku, however, the plaintiffs did not allege any injury caused solely by the RhoGAM injections.[7] Id. They alleged, instead, that their injuries were caused by "accumulated exposure [to] RhoGAM and thimerosal." Id. Thus, in Agbebaku, the plaintiffs expressly made a claim for accumulated exposure, and the court found those claims to be "clearly related" to the claims against the vaccine manufacturers. Id. at 29. Here, by contrast, the Does make no claim for accumulated exposure.

[7] In fact, the plaintiffs admitted that the children exposed to RhoGAM "were born 'perfectly normal and healthy.'" Agbebaku v. Sigma Aldrich, Inc., No. 24-C-02-004243, slip op. at 28 (Md. Cir. Ct. June 19, 2003), cert. denied, 844 A.2d 427 (Md. 2004) (quoting the complaint). Thus, any injury could not be attributable solely to RhoGAM and must have been caused by accumulated exposure.

Rather, the Does seek damages only for the injuries resulting from exposure to thimerosal in HypRho-D, and not for any injury from thimerosal contained in Minor Child Doe's vaccines. Contrary to Bayer's assertions, the Does do not seek a remedy for the full scope of their injuries in two courts. They have split their request for compensation into two parts and brought each request in the appropriate forum, as they are required to do by law.

Each forum in which the Does file recognizes a distinction between a preexisting condition and aggravation of that condition as separate injuries. Thus, each forum allows Plaintiffs to split their claims in this way. Under North Carolina law, recovery for an injury may be had separately from recovery for aggravation of that injury. See Howell v. Nichols, 22 N.C. App. 741, 743-44, 207 S.E.2d 768, 770 (1974) (stating that in a claim for aggravation of an injury, "the recovery is limited to the additional injury caused by the aggravation") (internal quotations omitted). Under the Vaccine Act, their claim for significant aggravation may be brought without seeking recovery for the preexisting condition. See 42 U.S.C. § 300aa-11(c)(1)(C). In these circumstances, the Does may pursue their claims separately.

It does not appear that the Does are attempting to evade the additional filing requirements or award limits in the Vaccine

Court. Plaintiffs' full spectrum of claims cannot be heard in a single proceeding. The Vaccine Court's jurisdiction is limited to petitions for vaccine-related injury. Plaintiffs do not allege that Minor Child Doe's preexisting injury was caused by vaccines, so the Vaccine Court has no jurisdiction to hear their preexisting injury claim. On the other hand, this court has no jurisdiction to hear Minor Child Doe's significant aggravation claim because the Vaccine Court has exclusive jurisdiction over claims for injuries caused by vaccines.

Nor does it appear that Plaintiffs can recover for the full scope of their injuries in this proceeding. Plaintiffs' claims here are somewhat limited in nature, and this limited nature will adequately frame the factual issues. Plaintiffs' recovery will be limited by their proof on causation because they can only recover for injuries they can show were the result of a single dose of HypRho-D. They will be required to show that their alleged damages "are the natural and probable result of" this single dose. Phillips v. Universal Underwriters Ins. Co., 43 N.C. App. 56, 58, 257 S.E.2d 671, 673 (1979). They will only be "entitled to compensation to the extent that [they have] established damages with as much certainty as the nature of the tort and the circumstances permit." Whiteside Estates, Inc. v. Highlands Cove, L.L.C., 146 N.C. App. 449, 462, 553 S.E.2d 431, 440 (2001) (internal quotations omitted). The injury for which

the Does seek compensation in this forum is separate and distinct from the injury at issue in the Vaccine Court and is not "vaccine-related."

b. Causation

Defendant next asserts the claims are vaccine-related because the causation issue is so similar in the two forums that no practical distinction can be made between them. Bayer argues that because both sets of claims hinge on the effects of exposure to thimerosal, both courts will be required to conduct the same discovery. (Bayer's Reply at 3.) Other factual issues relevant to both proceedings are the prenatal condition of Minor Child Doe, his condition at birth, the first manifestation of symptoms from the initial exposure, and the subsequent progression of any disease or disorder.[8] (Id. at 5.) Unlike many previous cases, in this situation the same causative agent is involved in both proceedings. (Id. at 4.) This will complicate the evidence because Plaintiffs must prove that HypRho-D alone caused their injuries, despite subsequent exposure to the same substance from other sources. (Id. at 3-4.)

Plaintiffs counter that they have brought two distinct claims, each involving its own factual inquiries, and each in its

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[8] Bayer also contends that the Vaccine Court is allowed to make a full review of all causation issues in deciding what caused the significant aggravation of any preexisting condition. (Bayer's Reply Pls.' Mem. Law Resp. Bayer's Mot Dismiss at 3.)

appropriate forum. (Pls.' Resp. at 8.) They argue that the cause of the preexisting condition and the cause of the "significant aggravation" are "completely separate issues." (Id. at 7.) Importantly, they assert the Vaccine Court cannot consider the cause of Minor Child Doe's preexisting condition because its jurisdiction is limited to vaccine-related injuries. (Id. at 5-6.) They also face a three-year statute of limitations for Minor Child Doe's vaccine-related claims, so they could not wait for resolution of this case before filing their Vaccine Court petition without risk of losing their right altogether to file in the Vaccine Court. (Id. at 9.)

Bayer's argument that the substantial overlap of discovery on causation should warrant dismissal of this action is without merit. In general, separate claims for injury and for aggravation of an original injury each may be supportable, even though "[t]he line between the consequences of completed past conduct and the impact of continuing or renewed conduct is itself blurred." 18 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure § 4409 (2d ed. 2002); see also, Warren v. Colombo, 93 N.C. App. 92, 96, 377 S.E.2d 249, 252 (1989) (recognizing an independent cause of action for "enhanced injuries"). Separating claims in this way may involve a difficult factual determination, but determinations of disputed factual questions are "historically . . . left to the jury upon

proper instructions." Word v. Jones ex rel. Moore, 350 N.C. 557, 563, 516 S.E.2d 144, 148 (1999). Thus, while Bayer may be correct that there will be substantial overlap and complications regarding causation here, the management of these issues is possible and has been adequately handled by courts in the past. Such difficulty does not justify dismissal of the claims.

Bayer also argues that the duplication of discovery on causation would be inefficient and wasteful. Multiple actions arising out of the same series of events can be expensive and wasteful of judicial resources. Afifi v. United States Dep't of Interior, 924 F.2d 61, 63-64 (4th Cir. 1991). "This puts increased burdens on the courts as well as the parties'" Id. at 63 (internal quotations and citations omitted). However, "federal courts have a strict duty to exercise the jurisdiction that is conferred upon them by Congress." Quackenbush v. Allstate Ins. Co., 517 U.S. 706, 716, 116 S. Ct. 1712, 1720 (1996). This duty is especially important when one of the parties could be prejudiced by a dismissal. See, e.g., Afifi, 924 F.2d at 63 (holding in a case where the plaintiff was mistaken in her belief that the district court had jurisdiction and where her right to appeal to the Federal Circuit on her administrative claims had passed, district courts should have discretion to retain jurisdiction over the case; also citing special concern to avoid leaving an "unlucky plaintiff" with no

recourse in a district court and a "long-expired appeal period to the Federal Circuit"). In Afifi, the Fourth Circuit Court of Appeals recognized that district courts ought to consider judicial economy in assessing whether they should retain jurisdiction over a case, but it also instructed district courts to consider fairness to the litigants and possible prejudice. Id. Here, Plaintiffs cannot bring their preexisting injury claim in the Vaccine Court because it is only authorized to hear petitions for "a vaccine-related injury or death." See 42 U.S.C. § 300aa-12(a). HypRho-D is not a vaccine and any injury resulting from its use is not "vaccine-related," so the Vaccine Court cannot hear this claim for Minor Child Doe's preexisting injury. Because Plaintiffs could not bring this preexisting injury claim in the Vaccine Court, it would be unfair for this court to refuse to hear it.

This court finds that Plaintiffs do not bring claims to recover for any "vaccine-related injury" and so are not covered by the Vaccine Act. Thus, Plaintiffs face no exhaustion requirements before filing in this court, and Bayer's motion to dismiss under Rule 12(b)(1) will be denied.

B. Bayer's First Alternate Motion to Stay Proceedings

As an alternative to dismissal, Bayer asks that the proceedings here be stayed pending resolution of Plaintiffs' claims in the Vaccine Court. (Bayer's Mot. Dismiss at 15.)

Bayer argues that without a stay, "there will inevitably be duplicative discovery with attendant expense and the risk of inconsistent outcomes." (Id. at 16.) Specifically, Bayer contends there will be duplication of discovery on Minor Child Doe's medical history, the causal role of vaccines, the causal role of thimerosal, and the causal role of HypRho-D. (Id.) In addition, Bayer argues that if Plaintiffs choose to file a civil action against the manufacturers of Minor Child Doe's vaccines after rejecting the Vaccine Court's judgment, there could be a third round of discovery. (Id.) Bayer asserts that Plaintiffs will not be prejudiced by a stay. (Id.) Plaintiffs respond that "the claims are separate and distinct, the same parties are not involved, the same issues are not controlling and there will be no duplication of efforts." (Pls.' Resp. at 19-20.)

A court has the power to stay proceedings, which is "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." Landis v. North Am. Co., 299 U.S. 248, 254, 57 S. Ct. 163, 166 (1936). In determining whether to exercise this power, a court "must weigh competing interests and maintain an even balance." Id. If there is a possibility that the stay could be detrimental to another party, then the movant must justify it by "clear and convincing

circumstances outweighing" such possible harm. Williford v. Armstrong World Indus., Inc., 715 F.2d 124, 127 (4th Cir. 1983).

In other cases where plaintiffs brought thimerosal claims in district courts which were related to a Vaccine Court petition, courts have been inconsistent in deciding whether to stay the district court proceedings. For example, in Doe 3 v. Ortho-Clinical Diagnostics, Inc., the Eastern District of North Carolina stayed its own proceedings. No. 7:03-CV-138-FL(1), slip op. at 8 (E.D.N.C. Jan. 7, 2004), recons. denied, No. 7:03-CV-138-FL(1), slip op. (E.D.N.C. Mar. 17, 2004). In Doe 3, the plaintiffs filed suit based on the use of thimerosal in an Rh-immune globulin product given to the mother 28 weeks into her pregnancy, and then administered to her a second time 72 hours after the birth. Id. at 2. In addition to the prenatal exposure, this second injection allegedly had the effect of exposing the infant to mercury after birth through breast milk. Id. at 5. The court found "no ready separation between pre-birth and post-birth exposure" in the case, and also found causation in the two proceedings to be "intertwined." Id. at 5-6. The exposures at issue in the case would be considered by the Vaccine Court, would be a subject of its discovery, and would be included in its findings. Id. at 6. In deciding that a stay would be appropriate, the court reasoned that a "parallel inquiry on a different timetable [would be] duplicative, expensive, and

wasteful of resources," and found there would be no prejudice to the plaintiffs because the Vaccine Court's Omnibus Autism Proceeding was scheduled to conclude in a matter of months. Id. at 6. At the time Judge Flanagan issued her opinion in Doe 3, the Omnibus Autism Proceeding was scheduled to conclude in July 2004. Autism General Order #1, 2002 WL 31696785 at *4. At this time, no results have been published and the proceeding appears to be ongoing. See Autism Discovery Ruling #1, 2004 WL 1660351 at *17 (noting in a ruling issued on July 16, 2004, that the court would continue working on the Omnibus Autism Proceeding and that a "status conference" was scheduled for August 10, 2004).

In Doe 2 v. Ortho-Clinical Diagnostics, Inc., Judge Beaty, writing for the U.S. District Court for the Middle District of North Carolina, denied a stay. 335 F. Supp. 2d at 636. The Doe 2 plaintiffs brought claims regarding the thimerosal contained in a prenatal injection of RhoGAM, and also for a post-birth injection and the resulting mercury exposure to the infant through breast milk. Id. at 618-19. In Doe 2, Judge Beaty refused to stay the district court proceedings because "the Vaccine Court's inquiry [was] independent of this Court's inquiry." Id. at 635. There would be no duplication of effort because the defendant had not been required to participate in the Vaccine Court's discovery process, and any discovery ordered by the U.S. District Court would have been required of the defendant

regardless of how discovery proceeded in the Vaccine Court. Id. Judge Beaty also reasoned that the prospect of inconsistent judgments was insufficient to warrant a stay because the Vaccine Court's decision could not bind the U.S. District Court. Id. at 636. Even if the child rejected the Vaccine Court's judgment and sought to bring the vaccine manufacturers into a civil proceeding, the Vaccine Act prohibited the district court's admission of the Vaccine Court's findings of fact, conclusions of law, final judgments, or any subsequent disposition on appeal. Id.; see 42 U.S.C. § 300aa-23(e). Judge Beaty allowed the proceedings to continue "at least for purposes of discovery on the issues related to RhoGAM," but said he would reconsider if future events in the Vaccine Court, such as a final ruling or the plaintiffs' rejection of a judgment, should warrant consolidation of multiple proceedings or would otherwise cause prejudice or waste the court's time. Id.

In arguing for a stay, Bayer points to cases such as Liu v. Aventis Pasteur, Inc., where courts have stayed the parents' derivative claims until the child's claims had been decided by the Vaccine Court. 219 F. Supp. 2d 762, 768 (W.D. Tex. 2002). The Liu court cited the need "to avoid interference with related proceedings in another forum and to avoid the waste of duplication." Id. In Liu, however, as in the other cases cited by Bayer, the stayed claims were for injuries allegedly caused by

thimerosal in vaccines. Liu, 219 F. Supp. 2d at 765; see, e.g., Blackmon v. American Home Products, Inc., 328 F. Supp. 2d 647, 650 (S.D. Tex. 2004) (describing claims brought for thimerosal contained in childhood vaccines); Botter v. Aventis Pasteur, Inc., No. 9:02-CV-181, slip op. at 2-3 (E.D. Tex. Jan. 15, 2003) (same); Carabine v. Aventis Pasteur, Inc., No. A-02-501-SS, slip op. at 2 (W.D. Tex. Oct. 8, 2002) (same); Russak v. Aventis Pasteur, Inc., No. A-01-CA-480-SS, slip op. at 2 (W.D. Tex. Sept. 9, 2002) (same); O'Connell v. American Home Products, Inc., No. G-02-184, 2002 WL 31455729, at *1 (S.D. Tex. May 7, 2002) (same). The claims in this case are more distinct from the Vaccine Court petition because the thimerosal at issue here was not contained in a vaccine and the exposure was entirely in utero.

On balance, Bayer has not shown that a stay is warranted. There is no indication that the discovery required of Bayer in the District Court regarding the in utero effects of thimerosal will be substantially duplicated in the Vaccine Court. Indeed, the discovery in the Vaccine Court is being conducted largely through the Omnibus Autism Proceeding, which may not involve the effects of in utero exposure to thimerosal in any way. Additionally, there is no indication that Bayer has been asked to participate in the Vaccine Court proceeding. To the extent that discovery required of Plaintiffs is duplicative, such as regarding Minor Child Doe's medical history, Plaintiffs have

effectively consented to such duplication and expense by filing multiple claims. Further, there is no indication that Bayer will be subject to inconsistent outcomes because Bayer is not a party to the Vaccine Court proceeding, and the Vaccine Court's resolution of its matter is not binding on the District Court. Finally, and in contrast to Bayer's assertion, Plaintiffs could be prejudiced by a stay issued for an uncertain period of time. The Vaccine Court has not published a revised schedule of its Omnibus Autism Proceeding, nor has it indicated when it expects to conclude that investigation, so a stay pending the resolution of Plaintiffs' petition could go on for years. It could be prejudicial to Plaintiffs if they are forced to wait unknown months or years for a resolution of their claims in the District Court. For these reasons, a stay will be denied at this time.

Bayer, however, does raise the important issue of efficiency. Although it appears that any such issues can be handled by standard procedural rules, the court will follow Judge Beaty's decision in Doe 2 by denying Bayer's motion to stay without prejudice to its right to refile. Bayer may refile if circumstances change, such as if Plaintiffs' Vaccine Court petition is resolved, and a stay appears necessary to avoid prejudice to itself or the waste of the court's time and resources.

C. Bayer's Second Alternate Motion for More Definite Statement under Rule 12(e)

As a second alternative to dismissal, Bayer asks for a more definite statement under Rule 12(e) of the Federal Rules of Civil Procedure. Bayer asserts that the Does' complaint omits information necessary to establish threshold defenses. (Bayer's Mot. Dismiss at 17-18.) Specifically, Bayer asks for the date of the HypRho-D injection, the fact that Plaintiffs have filed a petition in the Vaccine Court, the names and dates of Minor Child Doe's vaccinations that are at issue in the Vaccine Court proceeding, identification of Minor Child Doe's vaccinations that contained thimerosal, identification of all of the child's injuries, the dates of onset of the child's symptoms, and the date he was diagnosed as having a neurodevelopmental disorder. (Id. at 18-19.) The Does have included in their complaint that Cynthia Doe received an injection of HypRho-D on or about December 16, 1994. (Compl. ¶ 25.) Plaintiffs have acknowledged in their response to Bayer's motion to dismiss that they filed a petition in the Vaccine Court on October 15, 2002 (Pls.' Resp. at 6), but the petition remains sealed and it appears that Bayer has seen little information about it. Plaintiffs have only generally described Minor Child Doe's injuries.

Rule 12(e) allows a party to make a motion for a more definite statement "[i]f a pleading . . . is so vague or ambiguous that a party cannot reasonably be required to frame a

responsive pleading." Fed. R. Civ. P. 12(e). "The test is whether it is reasonable to require defendants to respond to the [pleading]." Gilbert v. Bagley, 492 F. Supp. 714, 749 (M.D.N.C. 1980). Rule 12(e) must be read in connection with Rule 8, which sets the minimum pleading requirements. Hodgson v. Virginia Baptist Hosp., Inc., 482 F.2d 821, 822 (4th Cir. 1973). Rule 8(a) requires that a pleading contain (1) "a short and plain statement of the grounds upon which the court's jurisdiction depends"; (2) "a short and plain statement of the claim showing that the pleader is entitled to relief"; and (3) "a demand for judgment." Fed. R. Civ. P. 8(a). Generally, a pleader need not go beyond the minimum requirements in Rule 8, but Rule 12(e) allows another party to ask for more information when it is necessary to properly respond. The purpose of these relatively low pleading requirements is "to reduce reliance on pleadings to refine the evidentiary basis for a litigant's claim." Hodgson, 482 F.2d at 823.

The Federal Rules of Civil Procedure do not require that a pleading allege any "facts," and the rules set out discovery procedures to ascertain relevant information. Id. There is a desire to prevent litigants from turning Rule 12(e) into a discovery substitute, and "courts will generally deny a motion for a more definite statement where the information sought may be obtained in discovery." Hilska v. Jones, 217 F.R.D. 16, 21

(D.D.C. 2003). Where a party has enough information to frame an adequate answer, a court should deny the Rule 12(e) motion and avoid delay in maturing the case. Hodgson, 482 F.2d at 824.

With regard to a request for more definite statement of dates, courts have shown a willingness to allow amendment if the date is definite, but have been less willing to allow amendment when dates are somewhat uncertain or when the events take place over a period of time. 5C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1376 (3d ed. 2004). See, e.g., Oresman v. G.D. Searle & Co., 321 F. Supp. 449, 458 (D.R.I. 1971) (granting motion for a more definite statement as to the date of a stroke, but denying it as to the dates of purchase of birth control pills, consumption of the pills, or onset of symptoms prior to the stroke); compare International Harvester Co. v. General Ins. Co., 45 F.R.D. 4, 7 (D. Wis. 1968) (granting motion for a more definite statement of dates when "each transaction took place at a fixed time") with Geir v. Educational Serv. Unit No. 16, 144 F.R.D. 680, 685-86 (D. Neb. 1992) (denying request for specific dates of each alleged instance of abuse and dates school officials became aware of abuse because such matters were more properly left for discovery); Porter v. Reynolds, 6 F.R.D. 536, 539 (N.D.N.Y. 1947) (denying request for date of each sales transaction in a claim

under the Emergency Price Control Act as unnecessary and more properly a matter for discovery).

It appears that Bayer has enough information to file an answer to the Does' complaint. Bayer has been sufficiently informed of the date of the HypRho-D injection and the nature of the Does' claims against it in this proceeding. Bayer should be able to frame a suitable response to each of the allegations. Most of the information Bayer requests, such as more information about symptoms, injuries, and Minor Child Doe's vaccination history, is somewhat indefinite and complicated, and is inappropriate to request at the pleading stage. Rather, this is the type of information that discovery procedures are designed to manage. Therefore, Bayer's motion for a more definite statement will be denied.

III. BAYER'S MOTION FOR PLAINTIFFS TO SUPPLEMENT RECORD

Finally, Bayer has requested that Plaintiffs supplement the record by filing with this court copies of all documents that were sealed by the state court prior to removal.[9] (Mot. Pls.' Supplement R. at 2-3.) Bayer asserts that when it removed the case from Durham County Superior Court certain documents had been sealed by that court, and so it was unable to verify that it had

[9] Plaintiffs originally filed their suit in the General Court of Justice, Superior Court Division, Durham County, North Carolina, Civil Action No. 03 CVS 3456. This court denied Plaintiffs' motion for remand in a Memorandum Opinion and Order issued November 1, 2004.

attached a complete copy of the state court file with its Notice of Removal, as is required by 28 U.S.C. § 1446(a). (Id.) Section 1446(a) requires that a defendant attach "a copy of all process, pleadings, and orders served upon such defendant" when removing a case. 28 U.S.C. § 1446(a). In a Consent Protective Order issued by this court on October 27, 2004, the court ordered Plaintiffs to submit to the court and all parties "a copy of all state court filings in this matter, said papers being filed under seal." (Consent Protective Order at 1.) The purpose of the protective order and the sealing of documents was to allow Plaintiffs to limit disclosure of their identities in the public record, and was not intended to limit or restrict discovery. (Id.) Because the Consent Protective Order has given Bayer the relief it requests in its motion to supplement the record, the motion is moot.

IV. CONCLUSION

For the reasons set forth above,

IT IS ORDERED that Defendant Bayer's Motion to Dismiss [4-1] is DENIED.

IT IS FURTHER ORDERED that Defendant Bayer's Alternative Motion to Stay [4-2] is DENIED without prejudice.

IT IS FURTHER ORDERED that Defendant Bayer's Second Alternative Motion for More Definite Statement [4-3] is DENIED.

IT IS FURTHER ORDERED that Defendant Eli Lilly and Company's Motion to Dismiss Plaintiff's Complaint [6] is DENIED AS MOOT.

IT IS FURTHER ORDERED that Defendant Bayer's Motion for Plaintiffs to Supplement Record [2] is DENIED AS MOOT.

This the 25 day of March 2005.

William L. Osteen
United States District Judge